Mixed Methods in Biomedical and Health Services Research

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Mixed-methods studies, in which qualitative[1] and quantitative methods are combined in a single program of inquiry,[2] are increasingly common and can be valuable in biomedical and health services research, in which the complementary strengths of each approach can characterize complex phenomena more fully than either approach alone.[3,4] To effectively address complex problems in health and healthcare delivery, including heterogeneous and dynamic systems of care, a multilevel approach is needed to capture the perspectives of patients, providers, and organizations. Mixed methods offer enhanced capabilities to this end. Consequently, interest in mixed-methods studies is growing among funders, as evidenced by recent calls for proposals using these methods from the National Institutes of Health (NIH),[5] the Agency for Healthcare Research and Quality,[6] and independent research organizations (eg, Patient Centered Outcomes Research Institute)[7] and foundations (eg, The Robert Wood Johnson Foundation).[8] Training in mixed methods is also sponsored by NIH,[9] the Agency for Healthcare Research and Quality,[10] and professional associations.[11] Nevertheless, written guidance on how to conduct rigorous mixed-methods research is not readily available to the general readership of peer-reviewed biomedical and health services journals, a group who may be less familiar with this approach.

Accordingly, in this article, we describe applications of mixed methods in biomedical and health services research and provide a concise overview of key principles to facilitate best practices. First, we define mixed-methods approaches and present illustrations from published literature, including cardiovascular care. Second, we summarize standards for the design and conduct of rigorous mixed-methods studies. Third, we highlight 4 central considerations for investigators interested in using these methods.

Mixed-Methods Research in Biomedical and Health Services Research: Approaches and Illustrations

Mixed methods can be useful in the pursuit of a broad range of focal topics and study aims in the biomedical and health services research arenas, including, but not limited to, clinical or quality issues,[12–14] healthcare organizational performance,[15] behavioral interventions,[16,17] processes of implementation of innovations,[18,19] healthcare decision making,[20] and measurement development for complex constructs.[21,22] Including a supplemental qualitative component within experimental or quasi-experimental studies of complex interventions is becoming increasingly common (see Lewin et al[17] for a review of qualitative methods within randomized, clinical trials). In this approach, the qualitative component can examine whether the intervention was delivered as intended, describe implementation processes, and generate understanding of why the intervention failed to work or how its effectiveness was promoted or limited in the real world. Qualitative findings can help mitigate publication biases against studies lacking intervention effectiveness by both explaining negative results and informing subsequent research. With regard to healthcare organizational performance, we are often seeking not only to measure performance or change in performance but also to understand why organizations perform well or poorly and what diverse types of factors might influence performance. Of particular importance is the careful matching of the method to the research question of interest. Illustrations from a variety of focal topics in the published literature, together with specific contributions of the qualitative and quantitative components to the overall research aim, are summarized in the Table.

Key factors in mixed-methods study design are the relative timing of when each method is carried out (concurrently or sequentially) and the emphasis accorded to each component for addressing the purpose of the study (whether the components are equally weighted or whether one is primary and the other secondary).[28] Whether in a concurrent or sequential design, several features characterize the connections between components in a mixed-methods study. These include (1) a priori intention to conduct the second component and integration of design elements to facilitate this linkage, (2) use of a common sample (eg, drawing a purposive sample for a qualitative study based on the survey results of the first quantitative component), (3) a unifying aim or research question, (4) the contingency of the questions/design of 1 study on the findings of the other, (5) the degree to which findings feed iteratively into the design or conduct of the other, and (6) the degree of integration of findings.[29]

There are 4 basic types of mixed-methods designs (the Figure).[2] The first is the sequential explanatory strategy in

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Table. Focal Topics Well Suited for Mixed Methods and Illustrative Studies

Focal Topic or Aim	Illustrative Study	Qualitative Component	Quantitative Component
Clinical or quality issue	Medication errors in computerized order entry systems[14]	Discover potential sources of error risk and characterize context in which errors occur	Quantify frequency of error risks reported by house staff
Organizational performance	Quality of AMI hospital care[23,24]	Describe complex processes and organizational environment	Identify factors associated with 30-day risk-standardized mortality rates
Complex intervention trials/RCTs	Secondary preventive follow-up care for patients with AMI or angina[25]	Clarify process and examine underlying theory to inform interpretation of quantitative results and future intervention designs	Assess impact of intervention on lifestyle and cardiovascular risk
Implementation science	Organizational readiness to adopt new protocol for acute stroke care[26]	Elicit patient and staff perceptions of facilitators and barriers to adoption	Assess organizational readiness with the Team Climate Inventory Questionnaire
Medical decision making	Informed consent for abdominal aortic aneurysm repair[20]	Characterize patient perspectives on informed consent process	Assess variation in surgeon reports and factors associated with variation
Develop quantitative measurement of a complex construct	Patient-centered measures of outcomes of treatment for prostate cancer[27]	Identify core facets of the phenomenon from patients' perspective	Develop and validate items and scales through psychometric testing

AMI indicates acute myocardial infarction; and RCT, randomized, controlled trial.

which the quantitative component is followed by a qualitative component and the qualitative results assist in explaining the findings of the quantitative study. For instance, in a quantitative study of patients with acute myocardial infarction (n=500), Spertus et al[30] found that 14% of patients receiving a drug-eluting stent discontinued clopidogrel, a life-sustaining antiplatelet drug, before the recommended duration despite potentially fatal consequences for early termination. To understand potential reasons for this patient behavior, Garavalia et al[31] conducted a qualitative study of patients with acute myocardial infarction who had discontinued either clopidogrel (n=11) or cholesterol-lowering therapy (n=29); findings informed the development of a guide to support patient–clinician communication about heart medications.[21]

The second design is the sequential exploratory strategy in which the qualitative component is followed by a quantitative component. For example, a study of hospital performance in care of patients with acute myocardial infarction comprised an initial qualitative component to characterize features of top-performing hospitals and to generate hypotheses about factors related to performance that were then tested in a nationally representative sample of hospitals. Aspects of the organizational environment (eg, creative problem solving) were identified in the qualitative component and statistically associated with lower risk-standardized mortality rates in the quantitative findings.[23,24]

The third design is the convergent parallel strategy in which the quantitative and qualitative data collection is concurrent, the components are given equal weight, and the 2 data sets are analyzed and compared. For example, Kerr et al[32] sought to gain a more complete understanding of the effectiveness of a Web-based intervention for heart disease self-management in decreasing inequalities in access to self-management support for patients with coronary heart disease. Patients with coronary heart disease (n=168) using a modified version of the Comprehensive Health Enhancement and Social Support tool were followed up in a prospective cohort design with complementary quantitative and qualitative components. Quantitative data identified factors statistically associated with use of the tool; these findings were integrated with qualitative data from in-depth interviews with a subset of participants (n=19) to understand how and why the identified factors influenced participants' use of the tool.

Finally, in the concurrent embedded strategy, quantitative and qualitative data collection occurs at the same time; however, one component is predominant. For instance, a randomized, controlled trial of a computerized decision support tool for patients with atrial fibrillation being considered for anticoagulation treatment included a qualitative process evaluation to provide insights into the process and progress of the trial and to inform monitoring and auditing decisions.[33] Nonparticipant observation and in-depth interviews with participants (n=30) generated critical information that led to the discontinuation of an intervention arm of the trial.

Standards for Designing and Conducting Mixed-Methods Research

Guidance for designing and conducting mixed-methods research is available in multiple reference texts[2,34,35] and journal articles,[3,36–38] some of which focus on health care.[39] In addition, the US NIH Office of Behavioral and Social Science Research recently commissioned a report defining best practices in mixed-methods research.[29] This report is intended to assist investigators in preparing competitive mixed-methods applications for support from the NIH, to guide review panel members in evaluating proposals that use these methods, and to serve as a resource to NIH institutes and centers as they consider potential contributions of mixed methods, plan new initiatives, and set priority areas for their science.

Central Considerations in Conducting Mixed-Methods Studies

Despite this available guidance, the quality and rigor of mixed-methods research in the published empirical literature are highly variable.[4] We highlight 4 central considerations for investigators seeking to conduct rigorous mixed-methods research: alignment of aims, methods, and research team capacity; attention to methodological standards for each component; articulation and implementation of plans for deliberate integration of qualitative and quantitative components;

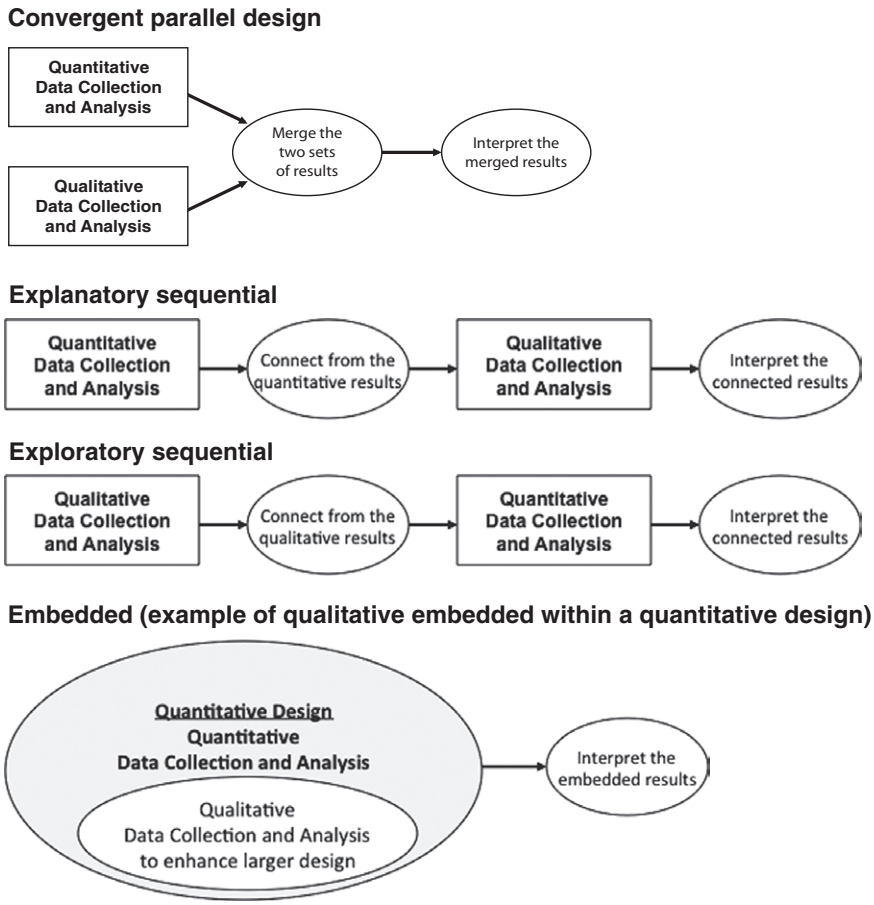

Figure. The major mixed-methods research designs. This figure is based on Creswell and Plano Clark's[2] discussion of mixed-methods designs. Adapted with permission from Sage Publications.

and adherence to recommended guidelines for writing mixed-methods papers.

Alignment of Aims, Methods, and Research Team Capacity

A mixed-methods study is best suited to address a multifaceted research aim (eg, one that seeks to generate evidence requiring distinct forms of measurement). For instance, a research goal to generate a model of health services use might use an exploratory sequential design with a qualitative component to identify core dimensions and to develop a theory and a quantitative component to test the theory. The motivation for a mixed-methods design must be explicit and compelling. Reasons might include the following: pursuing a topic about which little is known and hence using a qualitative component to inform hypothesis generation; producing a comprehensive account of the nature and magnitude of a phenomenon; seeking to both understand context and produce generalizable findings; aiming to describe both process and outcomes; and seeking increased confidence in findings by addressing threats to validity by either approach alone.[3] One recent review applied extant frameworks for the critical appraisal of published mixed-methods health services studies.[3] It found that only one third of reports provided justification for this design[40] and that only half did so in a review of mixed-methods mental health literature. In addition, each specific aim in a mixed-methods study should be substantive, rather than instrumental, in nature (eg, to explore reasons for patient nonadherence to an intervention protocol rather than to conduct patient focus groups).

Finally, the team composition and resources must be appropriate to achieve the study aims, including quantitative analysis, qualitative analysis, and integration strategies. Achieving optimal team composition is difficult because of the diverse areas of expertise required, and although quantitative expertise is typically present, mixed-methods research teams can suffer from underrepresentation of expertise in qualitative methods, mixed methods, or both. Even when the team composition is appropriate, the dynamics within such highly diverse teams may present challenges to effective collaboration, with the qualitative component undervalued or the mixed-methods aspect not well understood.[40,41] The time- and resource-intensive nature of mixed-methods designs is a notable challenge and must be explicitly recognized and planned for.

Adherence to Standards for Each Component

A central consideration in mixed-methods studies is the adherence to methodological standards for each component[2] The quantitative component must be designed and carried out with deliberate attention to principles of internal validity, external validity,[42] and reliability.[43] The qualitative research must be conceptualized and implemented in accordance with established principles for rigor (eg, to ensure credibility, transferability, and dependability).[44,45] Because these principles are distinctly different in qualitative and quantitative methods, explicit attention must be directed to adhering to the respective

standards for each component throughout the research process to ensure that key aspects of the design are not invalidated or undermined.[46] The risk of undermining these respective standards is heightened in mixed-methods studies, in which experts in quantitative methods may argue for large representative sample sizes (although inconsistent with principles for sampling in qualitative studies) or qualitative experts may criticize standardized quantitative data-collection instruments as introducing excessive researcher bias.

Integration of Findings Across Components

Essential to a mixed-methods approach is the deliberate mixing or integration of the quantitative and qualitative findings of each component,[2] and techniques to accomplish integration have been described; however, a lack of such integration persists in published research. The overall aim is to ensure that study components are directly linked and the output is synergistic, so that the end product is more than 2 parts alone.[47] Integration of findings from the qualitative and quantitative component can occur in all of the designs displayed in the Figure at the interpretation stages of a study, with one component explaining, enhancing, confirming, challenging, or quantifying findings from the other component. Alternatively, findings from one component may lead to further analysis within the other component, which in turn may lead to new insights.

Adherence to Recommendations for Reporting Mixed-Methods Research

A substantial challenge for researchers seeking to publish findings from mixed-methods studies in biomedical and health services journals is that space constraints often preclude full reporting of findings from both components in the same article.[48] A recent review of mixed-methods articles in health services research journals[4] found incomplete reporting of key methodological information. For instance, only 36% of mixed-methods studies reported the sampling selection for the quantitative component and 17% for the qualitative component; 40% reported the data analysis for the quantitative component and 31% for the qualitative component. One proposed template is Good Reporting of Mixed Methods Studies, which identifies the aspects of a study that should be addressed for appropriately transparent reporting, including the rationale for a mixed-method approach and a description of the design, the methods of each component, the procedures for integration, the limitations of each method, and insights gained from mixing methods.[40] Potential ways that researchers might convey this information are to make explicit linkages across articles if they are published as single reports, to request additional space if they are reporting both components in 1 article, and to use Web appendixes to provide additional information.

Conclusions

Mixed-methods approaches can be extraordinarily valuable to biomedical and health services research efforts. Studies using mixed methods can uncover novel causal factors, can open new areas of research, and can result in more flexible and holistic thinking about health and medicine. The methods are well established, and guidelines for reporting rigorous mixed-methods research exist. Application of rigorous mixed-methods research approaches can enhance our ability to understand and address the pressing issues of clinical care in an increasingly complex healthcare system.

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